IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

MONTGOMERY COUNTY, MARYLAND	*	
	*	
Plaintiff,		
v.	*	**Civil Action No. AW-06-477**
MIKE LEAVITT, *et al.*,	*	
Defendants.	*	

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MEMORANDUM OPINION

This action involves a suit by Montgomery County, Maryland ("County" or "Plaintiff") against Mike Leavitt ("Leavitt"), Secretary of Health and Human Resources, and Andrew C. von Eschenbach ("Eschenbach"), Acting Commissioner of the United States Food and Drug Administration (collectively, "Defendants"). The Complaint alleges that Defendants acted arbitrarily, capriciously, and abused their discretion, and otherwise acted in violation of 5 U.S.C. § 706, by failing to provide the County with a limited certification for a waiver under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") to implement a Canadian prescription drug reimportation program. The County also requests mandamus relief pursuant to 28 U.S.C. § 136, demanding that Leavitt discharge his "non-discretionary duty" to certify importation of Canadian prescription drugs under the MMA. Now pending before the court is Defendants' Motion to Dismiss [5]. The Court has reviewed the entire record, as well as the pleadings with respect to the instant motion. No hearing is deemed necessary. *See* Local Rule 105.6 (D. Md. 2004). For the reasons set forth below, the Court will grant Defendants' Motion to Dismiss.

I. FACTUAL AND PROCEDURAL BACKGROUND

In a letter dated October 10, 2005, County Executive Douglas M. Duncan, on behalf of Montgomery County, requested that Secretary Leavitt issue a waiver pursuant to the MMA to allow the residents of the County and its government to import prescription medications from Canada. (County Letter at 1.) The letter spoke of residents of Montgomery County who are forced to "choose between their health and putting food on the table" and stated that, while drug safety is a "first priority," the County believed it to be "fundamentally unfair that people living in Canada pay a fraction of what Americans pay for the same prescription." (County Letter at 1.)

Randall Lutter, the FDA's Acting Associate Commissioner for Policy and Planning, responded to the waiver request in a letter to Mr. Duncan, dated November 8, 2005. The FDA's response expressed concerns about the safety risks associated with the importation of prescription drugs from foreign countries, claiming that "many drugs that U.S. Consumers purchase from Canada and believe were made in Canada in fact originate from other countries such as India and Costa Rica." (FDA Letter at 1.) The letter also described the relevant provisions set forth in the Federal Food, Drug and Cosmetic Act ("FDCA") and asserted that "it is virtually certain that a foreign wholesaler or pharmacy would fail to comply with these applicable requirements, and therefore virtually every importation of such drugs would violate federal law." (FDA Letter at 1-2.) The letter mentioned prior communications between the Montgomery County Council and the FDA regarding the County's program, including the FDA's prior warning that the proposed program would not comply with the FDCA. (FDA Letter at 4.) Finally, the FDA letter pointed out that section 384 of the MMA "retains the requirement . . . that FDA may make effective a program for the importation of drugs by pharmacists and wholesalers only if the Secretary of Health and Human Services

("HHS") first certifies that implementing the program would (1) pose no additional risk to the public health and safety and (2) result in a significant reduction in the cost of drugs to the American consumer." (FDA Letter at 5) (citing 21 U.S.C. § 384). The FDA letter concluded that this certification requirement applies to the entirety of section 384, including the individual waiver provision, that it, therefore, "does not authorize a specific waiver for a discrete state pilot program," and, as a result, granting such a waiver would violate federal law. (FDA Letter at 5.)

On February 23, 2006, Montgomery County filed its Complaint with the United States District Court for the District of Maryland, alleging a violation of 5 U.S.C. § 706 and requesting mandamus relief pursuant to 28 U.S.C. § 136. Defendants filed a Motion to Dismiss Plaintiff's Complaint on April 26, 2006, and Plaintiff filed its Opposition to the Defendant's Motion on May 19, 2006. On June 2, 2006 Defendants filed their Reply.

II STANDARD OF REVIEW FOR A MOTION TO DISMISS

A court may grant a 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41 (1957). When reviewing a motion to dismiss, a court assumes "the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations" and examines only the legal sufficiency of the complaint. *Conley v. Gibson*, 355 U.S. 41 (1957). While the court must view the facts in a light most favorable to the plaintiff, the court "need not accept the legal conclusions drawn from the facts," nor should it "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Eastern Shore Markets, Inc. v. J.D. Associates Ltd. Partnership,* 213 F.3d 175 (4th Cir. 2000).

III. ANALYSIS

Montgomery County alleges that the FDA's decision to deny their waiver request for a Canadian drug importation program violated 5 U.S.C. § 706(2)(a), that the Secretary's failure to issue certification under 384(*l*) violated 5 U.S.C. § 706(2)(a), and that Mandamus relief is warranted because Defendants have failed to discharge their official duties. The Court will address these arguments in turn.

B. FDA'S DENIAL OF THE COUNTY'S WAIVER REQUEST WAS IN COMPLIANCE WITH APPLICABLE LAW AND, THERFORE, NO RELIEF CAN BE GRANTED WITH REGARD TO THIS CLAIM.

a. Standard of Review For Administrative Agency Action

Section 701(a) of the Administrative Procedure Act ("APA") provides that each agency or "authority of the government of the United States" is subject to judicial review except where " (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). In elaborating upon the second exception, the Supreme Court explained that "review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *see also Collins Music Co., Inc. v. United States*, 21 F.3d 1330, 1335 (4th Cir. 1994). The APA authorizes suit by a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute." *Id.* at § 702. Under the APA, the standard of review for challenging administrative agency action is whether the agency's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id.* at § 706(2)(a); *see Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000). The Supreme Court has interpreted this to be a narrow standard, holding that courts, in determining

whether or not an agency has violated section 706(2)(a), have "only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes." *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 97; *see also Wilson v. Office of Civilian Health and Medical Programs of the Uninformed Services*, 65 F.3d 361, 364 (4th Cir.1995). In this vein, the Fourth Circuit has repeatedly emphasized that the reviewing court "is not empowered to substitute its judgment for that of the agency." *E.g.*, *Zeneca, Inc.*, 213 F.3d at 167 (quoting *Citizens to Preserve Overton Park, Inc. v. Brinegar*, 494 F.2d 1212 (6th Cir. 1974)). The Supreme Court noted in *Consolo v. Federal Maritime Commission*, 383 U.S. 607, 620 (1966) that Congress deliberately adopted this standard of review because "it frees the reviewing courts of the time consuming and difficult task of weighing evidence, it gives the proper respect to the expertise of the administrative tribunal and it helps promote the uniform application of the statute."

b. Statutory Background

iii. Federal Food, Drug and Cosmetic Act

The FDCA establishes the Food and Drug Administration's ("FDA") comprehensive regulation of the manufacture, marketing, shipment, and labeling of drugs made in the United States. 21 U.S.C. § 301. Among other regulations, the FDCA stipulates that all "new drugs" must be approved by the FDA before they are marketed. *Id.* at §§ 321(p), 331(d), 355(a). To obtain such approval, a drug sponsor must establish, through carefully conducted clinical trials and other data, that the drug is safe and effective for each of its intended uses. *Id.* at § 355 (b); 21 C.F.R. Part 314. Also included in the approval process is an examination by the FDA of the manufacturing process and facilities, ingredients, strength and dosage form of the drug, containers, and labeling. *Id.* at §§

355(b)(1)(D), (d); 21 C.F.R. § 314.50. Even if a manufacturer has obtained approval for a drug, the version that the manufacturer produces for a foreign market is an unapproved drug if it has not been manufactured according to FDA stipulations, including those regarding packaging, dosage, and labeling requirements. *Id.* at §§ 331(a), (d); 21 C.F.R. § 314.50. Furthermore, anyone other than the original manufacturer who re-imports or causes the re-importation of FDA-approved drugs originally manufactured in the United States violates the FDCA. *Id.* at §§ 381(d)(1), 331(t).

ii. Medicare Prescription Drug, Improvement, and Modernization Act

The Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") was passed by Congress in 2003.[1] The Act provides that the Secretary of Health and Human Services, "after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." 21 U.S.C. § 384(b). The MMA also contains a provision allowing the Secretary to authorize waivers for individual importation: "The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate." *Id.* at § 384(j)(2). Section 384(*l*) of the MMA, however, requires certification by the Secretary of Health and Human Services before these provisions can take effect: "[t]his section shall become effective only if the Secretary certifies to the Congress that

[1] The MMA superseded the Medicine Equity and Drug Safety Act of 2000 ("MEDS Act"), which, similar to the MMA, authorized the Secretary of HHS to promulgate regulations that would allow pharmacists and wholesalers to import prescription drugs if the Secretary first certified that implementation of the provision would be safe and would reduce the cost of covered products. 21 U.S.C. § 384 (2003 Supp.). Former Secretaries Donna Shalala and Tommy Thompson declined to issue the certification.

the implementation of this section will (A) pose no additional risk to the public's health and safety; and (B) result in significant reduction in the cost of covered products to the American consumer." *Id.* at § 384(*l*). To date, the present Secretary, Michael Leavitt, as well as his predecessors, have failed to issue a certification under the MMA or the similarly designed MEDS Act.

c. The FDA's Decision Not To Grant The County's Waiver Request Was Not Arbitrary, Capricious, Or Otherwise Not In Accordance With the Law Because The FDA Was Legally Obliged To Deny The Request.

In this case, Plaintiff does not allege that its proposed program would comply with the FDCA but, rather, asserts that the FDA's decision to deny its waiver request for a Canadian prescription drug reimportation program under § 384(j)(2) of the MMA was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(a); (Compl. ¶ 2.) In pursuit of this claim, Plaintiff attempts three avenues of argument to address the language of 384(*l*), which requires the Secretary to issue a certification of safety and cost-effectiveness before 384 goes into effect. First, the County argues that the language of 384(*l*) does not refer to subsection (j), which stipulates that the government may grant waivers to individuals for the importation of prescription drugs. To support this claim, Plaintiff points to the language of 384(*l*), which is labeled "Commencement of Program" and provides, as was noted above, "this *section* shall become effective only if" the Secretary issues a certification as to the safety and cost-effectiveness of an importation program with Canada. 21 U.S.C. § 384(*l*) (emphasis added). Plaintiff argues that "section" does not refer to the entirety of section 384 but, rather, to several of the individual subsections, excluding 384(j). Plaintiff's argument that the 384(*l*) certification requirement does not apply to the section 384(j) waiver provision is blatantly contrary to the plain language of the statute. If Congress had intended the word "section" to refer only to particular subsections and not to section

384 as a whole, Congress would have specified to which subsections it was referring. Congress consistently distinguished between "section" and "subsection" throughout the MMA, and there is no reason to believe that it would not do the same with regard to the 384(*l*) certification provision.[2]

Plaintiff also contends that the term "program," from the title "Commencement of Program," refers only to the regulations provided for in subsection (b), regulations allowing for the importation of prescription drugs by wholesalers and pharmacies, but not to the individual waiver provision set forth in subsection (j). Plaintiff's basis for this argument is that "program" suggests a more comprehensive system of regulations, which would not include the issuance of individual waivers. Again, the Court presumes that Congress intentionally used the word "section" in the language of 384(*l*); therefore, the only reasonable interpretation of the word "program" is that it refers to the entirety of section 384, i.e. regulations affecting wholesalers, pharmaceutical companies, and individuals. This interpretation of the statute is consistent with the intent of Congress, as expressed in the Joint Explanation Statement of the Committee of Conference, which stated "The Conference Agreement . . . gives the Secretary, upon certification of safety and cost savings, authority to create a system for the importation of drugs from Canada by *pharmacists, wholesalers, and individuals*." H.R. Rep. No. 108-391, at 833 (2003), reprinted in 2003 U.S.C.C.A.N. 1808, 2185 (emphasis added). Thus, it is clear that Congress intended the certification provision to apply to both subsection (b) and to the individual waiver provision of subsection (j). Furthermore, although case law regarding the interpretation of section 384 is sparse, in a similar case in which the meaning of the section was disputed, the United States District Court for the District of Vermont ruled that the "only

[2] Congress recognized the distinction between "section" and "subsection" in the following provisions: *See e.g.* 384(c), (d)(1), (e), (g).

sensible way to read the statute is to assume that Congress intended the certification provision to apply to the whole of section 384." *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 475 (D. Vt. 2005) (holding that Vermont's proposed Canadian drug importation program would violate the FDCA and was not authorized by the MMA).

Besides pointing to the statutory language to support its claim that the certification requirement does not apply to the individual waiver provision in section 384(j), Plaintiff also points to a statement made by FDA Commissioner Mark McClellan ("McClellan") during an HHS Drug Importation Task Force Listening Session. McClellan remarked, in response to a statement made by Wisconsin Governor Doyle,

> [The FDA will] work with you in the waivers . . . I agree with you that people in this country should not be forced to choose between food and other needs . . . and I agree completely with you that we have an unfair system of drug pricing around the world that is putting too much of the burden on Americans. I am very much looking forward to working with you on some of these other steps that can be taken to address these concerns in addition to endorsing websites.

HHS Importation Task Force, Public Meeting, Transcript of Listening Session #3, April 14, 2004.[3] Plaintiff alleges that this statement is an endorsement by McClellan of the view that the FDA could issue waivers under section 384(j) prior to the section 384(*l*) certification. When examined in its proper context, it is clear that the "waivers" referred to by McClellan are not the same as the waivers mentioned in section 384(j) of the MMA. Rather, McClellan and Doyle were speaking of a waiver under which Wisconsin operates a Medicare senior care program, a program that does not rely on the importation of drugs from Canada. Mr. Doyle, in his remarks about the program, explained: "Most of our low and even low to moderate income seniors do not go to Canada, in Wisconsin,

[3] Available at http://www.hhs.gov/importtaskforce/session3/transcript.html

because we have such an effective senior care program." Thus, it is clear that McClellan could not have been referring to MMA waivers that allow for individual importation of prescription drugs from Canada. Moreover, even assuming arguendo that McClellan had been referring to the MMA waivers, Plaintiff offers no argument that the view of one official, which contradicts the plain language of the statute, as well as congressional intent, would be sufficient evidence to indicate an alternative meaning.

The third avenue Plaintiff pursues to address the certification caveat set forth in 384(*l*) is the argument that the FDA's failure to enforce the FDCA in some situations constitutes *de facto* certification by the Secretary. This argument also must fail for several reasons, including that the language of the statute in no way provides for the possibility of *de facto* certification but, rather, affords the Secretary sole discretion to issue certification. Additionally, it is well established that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," *Heckler v. Chaney*, 470 U.S. 821, 831 (1985), and, therefore, selective enforcement cannot be used as an argument for *de facto* blanket certification. The reasonableness of the Agency's actions, despite its failure to enforce the Act in all situations, has been reaffirmed by other courts that have considered the matter, including the United States District Court for the District of Vermont, which found that the FDA's denial of an MMA waiver request was proper and granted the government's motion to dismiss, *Vermont*, 405 F. Supp. at 474-75, 479, as well as by the United States District Court for the District of Columbia, which dismissed a complaint challenging the Secretary's continued evaluation of whether to issue the certification. *Andrews v. HHS*, No. 04-0307, 2005 U.S. Dist. LEXIS 5710 (D.D.C. March 31, 2005) *1, *2, *10.

Given that the MMA clearly provides that section 384, in its entirety, will not take effect until the Secretary of Health and Human Services certifies the safety and cost-effectiveness of a Canadian prescription drug importation program, the FDA's denial of the County's waiver request was mandated by federal law, and the FDA cannot be found to have violated 5 U.S.C. § 706(2)(a). Because Plaintiff can prove no set of facts in support of this claim which would entitle it to relief, the Court must dismiss Plaintiff's claim that the FDA's denial of the waiver request was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" under 5 U.S.C. § 706(2)(a).

C. THE SECRETARY'S FAILURE TO ISSUE CERTIFICATION UNDER § 384(*l*) IS NOT REVIEWABLE BY THE COURT, AS CERTIFICATION IS DISCRETIONARY.

The County also seeks judicial review of the Secretary's failure to issue a certification under section 384(*l*)(1), contending that the Secretary's failure to do so violates 5 U.S.C. § 701(a)(2).

a. Judicial Review Of An Administrative Agency's Failure To Act

Along with providing relief for agency action, section 706(1) of the APA provides relief for a failure to act: "the reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). The Supreme Court has held that a "'failure to act' is properly understood to be limited . . . to discrete action," meaning that "a claim under 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is *required to take*." *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 62-64 (2004) (emphasis added). The Court expounded that "the limitation to required agency action rules out judicial direction of even discrete agency action that is not demanded by law." *Id.* at 66. Similarly, the Fourth Circuit has held that judicial review is not available where an agency may act but fails

to do so, noting that "the use of precatory language makes it impossible to ascertain a standard against which the action or inaction of the [agency] can be measured." *Collins Music Co., Inc.*, 21 F.3d at 1335.

b. The Secretary's Failure to Certify Is Not Reviewable Because the Secretary Was Not Required To Issue Certification.

Subsection (*l*) of the MMA, labeled "Effectiveness of the Section," provides that "this section [384] shall become effective only *if* the Secretary certifies to the Congress that the implementation of this section will- (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(*l*) (emphasis added). The Act does not state that the Secretary must issue certification, nor does it provide a timeline within which the Secretary should consider the two issues to be examined and arrive at a decision as to certification. Congress could have made section 384 effective immediately upon enactment or set forth a timeline for certification, but it did not. After the previous two Secretaries of Health and Human Services failed to issue certification under the similarly designed MEDS Act, Congress could have altered the precatory language in the superseding MMA to make the Act effective immediately or to compel a decision as to certification by a certain date, but it chose not to. This is a legislative policy decision that must be brought before Congress, rather than before this Court. Given that the language set forth in 384(*l*) is precatory, rather than a discrete action that the Secretary is required to take, judicial review is not available to examine the Secretary's failure to issue certification.

Moreover, even if the Secretary's certification were considered a required agency action, judicial review is also foreclosed where statutes are so broad that "in a given case there is no law to apply," *Heckler*, 470 U.S. at 830, or where the court "could have no meaningful standard against

which to judge the agency's exercise of discretion." *Webster v. Doe*, 486 U.S. 592, 599 (1988). The MMA provides that section 384 will come into effect if the Secretary certifies that "the implementation of the section will (a) pose no additional risk to the public's health and safety; and (b) result in a significant reduction in the cost of covered products to the American Consumer." 21 U.S.C. § 384(*l*). The Act does not provide a method of evaluation or standards by which to measure "safety" or "significant reduction in cost." The broad language of subsection (*l*) provides the Court with no guidelines or standards by which to examine whether or not the Secretary's failure to issue certification up to this point is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(a). Therefore, the Secretary's decision as to certification is not reviewable because certification is discretionary and, even if it were not, the language of the MMA provides no "meaningful standard" by which to measure the Secretary's decision as to certification.

D. DEFENDANTS ACTED IN ACCORDANCE WITH THEIR ADMINISTRATIVE DUTIES UNDER THE LAW AND, THEREFORE, MANDAMUS RELIEF WILL NOT BE GRANTED.

Courts have long held that the remedy of mandamus is "a drastic one reserved for extraordinary situations involving the performance of official acts or duties." *United States ex. Rel. Rahman v. Oncology Assoc., P.C.*, 201 F.3d 277, 286 (4th Cir. 1999). The Supreme Court has explained that "[u]nder the established rule, the writ of mandamus cannot be made to serve the purpose of an ordinary suit. It will issue only where the duty to be performed is ministerial and the obligation to act peremptory and plainly defined. The law must not only authorize the demanded action, but require it; the duty must be clear and indisputable." *United States v. Wilbur*, 283 U.S. 414, 420 (1930), *see also Central South Carolina Chapter, Soc'y of Prof'l Journalists, Sigma Delta*

Chi v. U.S. Dist. Ct. for the Dist. of South Carolina, 551 F.2d 559, 561-62 (4th Cir. 1977). To establish the conditions necessary for issuance of a writ of mandamus, the party seeking the writ must show that "(1) he has a clear and indisputable right to the relief sought; (2) the responding party has a clear duty to do the specific act requested; (3) the act requested is an official act or duty; (4) there are no other adequate means to attain the relief he desires; and (5) the issuance of the writ will effect right and justice in the circumstances." *United States ex. Rel. Rahman*, 201 F.3d at 286 (citing *Kerr v. United States Dist. Court for the Northern Dist. of Cal.*, 426 U.S. 394, 402 (1976).

Mandamus is not justified in this case, as the Secretary has no duty to issue the section 384(*l*) certification. The language of the Act reads that the "section shall become effective only *if* the Secretary" issues a certification. 21 U.S.C. § 384(*l*) (emphasis added). The language of the Act in no way compels certification within a certain timeframe or demands justification for failure to certify. In fact, unless the Secretary determines that implementation of section 384 would pose no additional risk to public health and safety and would result in a significant reduction in cost for American Consumer, he is not at liberty to issue certification. To date, the Secretary has not presented findings that such requirements have been met. Rather, the 2004 report published by the Department of Health and Human Services arrived at very different conclusions.[4]

[4] The MMA mandated a study on the importation of drugs, which HHS and the FDA completed in December 2004. The report concluded, in part, that "total savings to consumers from legalized importation under a commercialized system would be a small percentage relative to total drug spending in the U.S. (about 1 or 2 percent)" and that "savings going directly to individuals would be less than 1 percent of total spending." HHS Report On Prescription Drug Importation, at 65 (2004). Furthermore, with regards to the safety of an importation program, the report concluded that the "[l]egalized importation of drugs in such a way that creates an opening in the 'closed' system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight and of drug regulation and the distribution system have been exploited." *Id.* at X. In reference specifically to the MMA and the 384(*l*) safety certification, the report found that much more needed to be accomplished before certification would be appropriate: "For the Secretary to make a safety certification, sufficient alternative safe guards would have to be imposed to ensure that imported drugs meet the same level of safety as drugs approved under section 355. Such alternative safeguards would not only have to be developed and implemented in the importation context, they would also have to be determined to be equivalent to the existing standards under 355." *Id.* at 26.

Plaintiff argues that "Defendant's current stance of refusing to issue certification while simultaneously allowing illegal re-importation constitutes a choice to preserve the status quo," that Congress changed the status quo by passing the MMA, and that Defendants, therefore, have a statutory obligation to trigger legal importation from Canada by issuing a certification under 384(*l*). This Court finds, however, that the language of section 384 is clear: a change in policy towards the legal importation of prescription drugs from Canada depends on the Secretary's certification that the two requirements set forth in section 384(*l*) have been met. Until this certification is issued, the current policy, which views as illegal almost all importation of prescription drugs, remains effective and the status quo remains intact. Moreover, as was previously discussed, enforcement by the FDA is discretionary and selective enforcement is not reviewable. *See Heckler*, 470 U.S. at 831. Accordingly, selective enforcement cannot be used as an argument to compel blanket enforcement.

Plaintiff cites several cases in an attempt to buttress its claim for mandamus relief. These cases are inapposite, as they all involve situations in which government agencies failed to perform clearly defined ministerial duties. *See Estate of Mansy Michael v. Lullo*, 173 F.3d 503 (4th Cir. 1999)[5]; *Naporano Metal & Iron Co. v. Secretary of Labor*, 529 F.2d 537 (3d Cir. 1976)[6]; *Ganem v.*

[5] Court found that District Director [of the IRS] "had no discretion in allowing the foreign death tax credit; instead the tax code mandates this credit: 'The tax imposed by section 2001 *shall* be credited with the amount of any estate, inheritance, legacy, or succession taxes actually paid to any foreign country.' I.R.C. 2014(a)." Court granted mandamus, holding: "Given the Director's lack of discretion, along with the baselessness of the I.R.S.'s actions, the Director had a clear duty to act as the Estate has requested." *Estate of Mansy Michael*, 173 F.3d at 513.

[6] Department of Labor denied an application for labor certification filed on behalf of an alien employee. Court found that Secretary was required to perform his duty of certification under the statute, where certification was mandated if certain requirements were met and the final requirement (that certification of employment would not 'adversely affect the wages and working conditions of the workers in the United States similarly employed') was definitively met because wages were established by a negotiated collective bargaining agreement. Court held, therefore that Secretary had no discretion to exercise. Rather, "once having determined that the alien is subject to the agreement and receives no less than his non-alien colleagues, the Secretary is required to perform his legal duty of certification under the statute."

Heckler, 746 F.2d 844 (D.C. Cir. 1984)[7].

Here, in contrast to the aforementioned cases, the Secretary's certification under 384(*l*) is not a ministerial duty or an official obligation. The language of 384(*l*) does not mandate such certification, nor does it set a timeline for the issuance of certification. The language of the MMA suggests that certification shall be issued purely at the discretion of the Secretary and that such certification is contingent upon findings of safety and cost-effectiveness on the part of the Secretary. To date, the Secretary has presented no such findings and has refrained from issuing certification. Such actions are not in violation of the MMA as Congress has adopted it. Should Montgomery County, or others in a similar position, wish to compel greater change in prescription drug importation policy, it is with Congress and the language of the MMA that they must take issue, and not with the Secretary's actions, which are in compliance with the Act. Because the action demanded by the County is discretionary, rather than mandated by law, a writ of mandamus may not be issued and the Court must dismiss the Plaintiff's claim for such relief.

[7] Court held that the Secretary of HHS, as the administrator of the Social Securtity Act, had a "statutory responsibility to make findings on the nature of Iran's social insurance system" so that it could be determined whether or not certain alien non-residents were entitled to benefits. *Ganem*, 746 F.2d at 854. The court reasoned that "[i]t is simply not within the Secretary's discretion to deprive entitled beneficiaries of their earned rights by virtue of a policy position that virtually assures the Secretary's inability to make a determination which the statute *obligates* her to make." *Id.* (emphasis added). In issuing this opinion, the court emphasized that mandamus should only be employed "to compel an officer to perform a purely ministerial duty." *Id.* at 853.

IV. CONCLUSION

For all of the aforementioned reasons, the Court will grant Defendant's Motion to Dismiss [5]. An order consistent with this memorandum opinion will follow.

Date: August 22, 2006

/s/
Alexander Williams, Jr.
United States District Court